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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,463

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Andreas Hartlep

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7155

7590

07/05/2006

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EXAMINER

HORWAT, JENNIFER A

ART UNIT

PAPER NUMBER

3768

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/661,463	<b>Applicant(s)</b> HARTLEP ET AL.	
	<b>Examiner</b> Jennifer Horwat	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6-12,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-12,14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 3/29/2006 have been fully considered but they are not persuasive. Applicant argues that the disclosure of Kucharczyk does not include function imaging for the use of navigation. However, as stated in the previous office action dated 11/30/2005, the examiner states that Kucharczyk discloses functional imaging (col 11, lines 55-63). Kucharczyk states that the method provides for "real-time imaging of brain function and heart function during interventional endovascular procedures, particularly where interventional devices such as catheters are...directed sequentially through one or more organs or body parts to perform a diagnostic or therapeutic procedure" (col 11). Further, Kucharczyk states that "image" means data that represents "the spatial layout of anatomical or functional features of a patient" (col 12, lines 18-20) and that "registration" means an alignment process by which two images are positioned coincident with each other so that corresponding points appear in the same position on the registered images (col 12, lines 27-30). Therefore, it is understood that Kucharczyk does in fact disclose these features.

### ***Claim Objections***

2. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

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dependent form, or rewrite the claim(s) in independent form. Claim 6 is dependent on cancelled claim 4. Claim 6 is interpreted for the purposes of examination as being dependent on claim 1.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk, et al (US 6298259) in view of Howard, III (US 6129685) and further in view of Howard, III (US 5820588). The invention of Kucharczyk discloses the invention substantially as claimed except for the invention being related to planned stimulation with specific regard to the manifestation of systemic tinnitus. Kucharczyk discloses a method for planning the stimulation of cortical regions including imaging structural features (col 2, lines 24-29) and imaging functional regions (col 11, lines 55-63). The method of Kucharczyk is capable of detecting brain function (col 11, lines 55-63) and, therefore, would be capable of detecting hyper/hypometabolic cortical areas.

Kucharczyk discloses registration of image sets (col 17, lines 28-33) and referencing the position of different cortical areas as part of a medical navigation system (col 17, lines 13-17; col 17, lines 33-49). The invention of Kucharczyk is capable of planned stimulation. Kucharczyk discloses the navigation system as being capable of magnetically detecting positional coils (col 17, lines 17-28). Kucharczyk discloses a medical probe capable of cortical stimulation (col 12, lines 6-16). Kucharczyk discloses

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the method as determining navigation data as well as targeted or optimal regions for stimulation wherein a computer manages the data output (col 17, lines 4-8; col 11, lines 16-21) and wherein the computer has a storage medium (col 14, line 66- col 15, line 3). Kucharczyk discloses stimulation a field distribution and determining stimulation areas (col 13, lines 12-40). Kucharczyk discloses calibrating the probe within the framework of planning, i.e. determining the initial position of the probe (col 16, line 18-20). Kucharczyk discloses that the use of optical imaging in surgical navigation (col 10, lines 38-43).

Howard, III (5820588) discloses a method for stimulation of regions in the auditory cortex in order to reduce the effects of tinnitus (col 7, lines 42-45).

Howard, III (6129685) discloses a method for planning stimulation of cortical regions including the primary auditory cortex wherein an electrode assembly having a magnetic tip is moved into a desired position within the target tissue by application of a magnetic field outside the patient's body (col 12, lines 24-31). Howard discloses a method for determining physiological patient data via this imaging method (col 20, lines 49-63) and would be capable of detecting positions of the hyper/hypometabolic cortical areas. Howard discloses methods for determining anatomical data and the position of the stimulator (col 12, lines 50-56). Howard discloses methods for stimulation of localized regions of the auditory cortex (col 14, lines 56-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the planned stimulation surgical method of Kucharczyk with the teachings of Howard, III such that the method included planned

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stimulation of areas related to systemic tinnitus for the purpose of delivering electrical signals in order to reduce clinically significant auditory phenomena caused by tinnitus, a disorder that affects 9 million Americans with 2 million of those being severely disabled by the disorder (Howard, III (5820588), col 6, lines 36-45).

5. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk in view of Howard, III as applied to claim 1 above, and further in view of Hochman (US 6196226). The modified invention of Kucharczyk, as discussed above, substantially discloses the invention as claimed except for the functional image detection method including at least one of a functional magnetic resonance image detection and a positron emission tomography (PET) and the methods including optical navigation. Hochman discloses methods including optically identifying and providing information regarding areas of cortical activity that could aid in the positioning of a probe or stimulator (col 4, lines 25-35). Hochman discloses the use of magnetic resonance (col 22, lines 17-21; col 12, lines 56-65) and discusses determining functional information from cortical areas (col 4, lines 8-12), rendering it obvious to apply functional magnetic resonance for the same purpose. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the planned stimulation surgical methods of Kucharczyk with the teachings of Hochman such that the methods included the use of functional magnetic resonance imaging and optical navigation and detection of markers for the purpose of being able to properly position the stimulator probe to the cortical area of interest and obtain the desired physiologic result.

***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

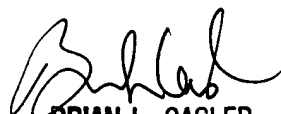
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-Th 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jah  
6/22/06

  
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